

EXHIBIT N

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7 UNITED STATES DISTRICT COURT
 8 CENTRAL DISTRICT OF CALIFORNIA

9
 10 UNITED STATES OF AMERICA ex
 rel. AIDS HEALTHCARE

CV04-0216 ABC (MANX)

11 FOUNDATION,) Case No.:
 12 Plaintiffs,) FILE UNDER SEAL PURSUANT TO 31
 13 vs.) U.S.C. SECTION 3730(b) (2)
 14 SERONO, INC.; DOES 1 TO 50,) DO NOT PLACE IN PRESS BOX
 15 Defendants) DO NOT PLACE IN PACER
 16)
 17) FALSE CLAIMS ACT COMPLAINT AND
 18) DEMAND FOR JURY TRIAL
 19)
 20)
 21)
 22)

1. AIDS Healthcare Foundation (the "relator") brings this
 action on behalf of the United States of America against
 defendants for treble damages and civil penalties arising from
 the defendants' false statements and false claims in violation
 of the Civil False Claims Act, 31 U.S.C. Sections 3729 et seq.
 (the "Act"). The violations arise out of false claims to the
 Medicaid and Medicare programs for the drug Serostim,
 manufactured and marketed by defendant Serono, Inc. ("Serono").

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 Complaint

1 2. As required by the Act, the relator has provided to
2 the Attorney General of the United States and to the United
3 States Attorney for the Central District of California a
4 statement of material evidence and information related to the
5 complaint. Because the statement includes attorney-client
6 communications and work product of relator's attorneys, and is
7 submitted to the Attorney General and to the United States
8 Attorney in their capacity as potential co-counsel in the
9 litigation, the relator understands this disclosure to be
10 confidential.

11 3. This action arises under the False Claims Act. This
12 Court has jurisdiction over this case pursuant to 31 U.S.C.
13 Sections 3732(a) and 3730(b). This court also has jurisdiction
14 pursuant to 28 U.S.C. Sections 1331 and 1345.

15 4. Venue is proper pursuant to the Act, 31 U.S.C. Section
16 3732(a), because the acts prescribed by the Act and complained
17 of herein took place in this district.

18 5. Relator is a non-profit corporation registered to do
19 business and doing business in the State of California. Its
20 non-profit mission is to provide medical treatment and advocacy
21 to people with HIV/AIDS and their families regardless of ability
22 to pay. AHF brings this action based on direct, independent
23 knowledge and also on information and belief.

24 6. AHF is an original source of this information to the
25 United States. It has direct and independent knowledge of the

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1 information on which the allegations are based and has
2 voluntarily provided the information to the Government before
3 filing an action under the False Claims Act, which is based on
4 the information.

5 7. The United States of America provides payment for
6 medical care to qualifying citizens under the Medicaid and
7 Medicare programs. Medical providers, pharmacists, and
8 pharmacies, among others, make claims for reimbursement for
9 services from monies provided in part by the United States under
10 the Medicaid and Medicare programs. These programs are the

11 primary payors for people with HIV/AIDS in California, if not
12 the entire country.

13 8. Defendant Serono is a pharmaceutical company. It
14 manufactures, distributes, and sells a drug called Serostim, and
15 related products. Upon information and belief, Serostim is a
16 type of growth hormone. One of the purposes for which Serostim
17 is used is to combat a syndrome called AIDS wasting, which can
18 afflict people with HIV/AIDS.

19 9. AHF has a long history criticizing the appropriateness
20 and use of Serostim for this purpose. AHF has taken the
21 position that, for people with HIV/AIDS, use of Serostim is
22 rarely justified or useful. Moreover, given its steep price of
23 as much as \$6,000.00 per month and negligible effect, the drug
24 is ripe for fraud, abuse, and black market dealings. Further,
25 the unnecessary use of the drug limits the amount of Medicaid

Complaint

1 and Medicare funds available for more beneficial medical
2 treatments for people with HIV/AIDS.

3 10. AHF has worked closely with State and federal
4 governments to assure appropriate use of Serostim for AIDS
5 wasting. AHF provided the California Attorney General's office
6 with declarations for use in litigation surrounding Serostim,
7 and has met with and provided information to the United States
8 Department of Justice regarding Serono and Serostim.

9 11. AHF has learned that Serono has engaged in practices
10 specifically designed to increase the use and prescribing of

11 Serostim to people with HIV/AIDS, even when not medically
12 appropriate. These practices include but are not limited to:

13 A. Providing pharmacists with a "rebate" in exchange
14 for providing demographic information for patients
15 prescribed Serostim, including the identity of the
16 prescriber of the drug. This allowed Serono to aggressively
17 market and solicit the prescriber, in order to increase
18 sales and use of the drug. These "rebates" could be up to
19 \$300.00 per month per prescription, a fee completely in
20 excess of the amount of time and effort involved in
21 providing the data to Serono;

22 B. Employees and/or agents for Serono would provide
23 guidance to providers on completing paperwork, known as
24 Treatment Authorization Requests or "TAR's," required for
25 the Medi-Cal program to pay for Serostim prescriptions for

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1 Medicaid recipients. These employees/agents actually
2 assisted the providers in filling out the forms, and
3 instructed them on what terms and items were necessary in
4 order for the TAR to be approved, and for Medi-Cal to pay
5 for the prescription.

6 C. As this medication ostensibly was prescribed for
7 AIDS patients to combat a syndrome known as "AIDS wasting,"
8 evidence of this wasting needed to be obtained. A primary
9 method of evidencing wasting is the use of a Bio-impedance
10 Analysis or "BIA," which measures a person's body mass index

11 (a measurement of fat to muscle). Equipment used to measure
12 this can cost thousands of dollars, and requires a person
13 trained in nutrition sciences to properly operate the
14 equipment to achieve correct results, and properly interpret
15 the results. Serono piloted a program whereby it offered
16 free tests of BIA to providers. Persons trained, employed,
17 and/or working under the auspices of Serono brought these
18 machines into the offices of providers, performed tests on
19 patients, recorded and then interpreted the results to the
20 providers. This is an inherent conflict of interest, and
21 the accuracy and veracity of any tests performed in such
22 matter is suspect, as well as any prescription for Serostim
23 based in part on the result of this tests.

24 12. In essence, Serostim created a complete assembly line
25 devised to do one thing - manufacture prescriptions for

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1 Serostim. From the information provided by the pharmacies,
2 Serono could identify and target doctors already predisposed to
3 prescribe the drug. It then manufactured medical results showing
4 a need for the drug, and then assisted in writing and completing
5 documentation so that the prescriptions would be covered by
6 Medicaid and/or Medicare.

7 13. By engaging in these practices, Serono knowingly
8 misled the government, and knowingly assisted in misleading the
9 government, into paying for prescriptions for Serostim that were
10 not necessary.

11 First Cause of Action

12 (Violation of 31 U.S.C. Section 3729)

13 14. AHF realleges and incorporates the allegation of
14 paragraphs 1 - 13 as if fully set forth herein.

15 15. By its conduct, Serono caused to be presented to the
16 United States Government a false or fraudulent claim for payment
17 or approval.

18 16. By its conduct, Serono knowingly made, used, or caused
19 to be made or used a false record or statement to get a false or
20 fraudulent claim paid or approved by the Government.

21 17. Serono combined, conspired, and agreed with other
22 persons and entities to defraud the United States by assisting
23 in submitting false claims to the United States and to its
24 grantees for the purpose of getting the false or fraudulent
25 claims for prescriptions for Serostim paid or allowed and

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1 committed the other overt acts set forth above in furtherance of
2 that conspiracy.

3 18. The above conduct is in violation of 31 U.S.C. Section
4 3729(a), causing damage to the United States.

5
6 WHEREFORE, AHF respectfully requests the Court to enter
7 judgment against defendants, as follows:

8 (a) That the U.S. be awarded damages in the amount of three
9 times the damages sustained by the U.S. because of the
10 false claims and fraud alleged within this Complaint;

11 (b) That civil penalties of \$11,000.00 be imposed for each
12 and every false claim that Serono caused to be
13 presented or assisted in presenting to the U.S. and/or
14 its grantees;

15 (c) That pre- and post-judgment interest be awarded, along
16 with reasonable attorneys' fees, costs, and expenses
17 which AHF necessarily incurred in bringing and pressing
18 this case;

19 (d) That the Court grant permanent injunctive relief to
20 prevent any recurrence of the False Claims Act for
21 which redress is sought in this Complaint;

22 (e) That AHF be awarded the maximum amount allowed to it
23 pursuant to the False Claims Act; and

24 (f) That this Court award such other and further relief as
25 it deems proper.

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1
2 DEMAND FOR JURY TRIAL

3 AHF, on behalf of itself and the United States, demands a
4 jury trial on all claims alleged herein.

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6 Dated this 13th day of January,
7 2004

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10 Foundation
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13 Los Angeles, CA
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